K042386

DEC 15 2004

510(k) Summary

as required by 807.92

1. Company Identification

Konica Minolta Medical & Graphic, Inc.
2970 Ishikawa-machi, Hachioji-shi, Tokyo 192-8505, Japan
Tel : 81-426-60-9607
Fax: 81-426-60-9588

2. Official Correspondent

Koji Kubo (Mr.)
Department TS
Production Technology Division
R&D Center

3. Date of Submission

August 31, 2004

4. Device Trade Name

Direct Digitizer REGIUS MODEL 190

5. Common Name

Direct Digitizer

6. Classification

Medical image digitizers were reviewed by the Radiology Panel and are classified in Class II per 21 CFR 892. 1650.

7. Predicate Device

The Direct Digitizer, REGIUS MODEL 190 is substantially equivalent to our Konica Direct Digitizer REGIUS MODEL170, 510(k) number: K023061. Comparison of the principal characteristics of the two devices is shown in the Appendix 1 Cross-reference table.

8. Description of Device

The Direct Digitizer, REGIUS MODEL 190 is an X-ray image reader which uses a stimulable phosphor plate (Plate) as X-ray detector installed in a separate cassette, and reads the image recorded on the Plate by inserting a cassette in the entrance slot of the REGIUS MODEL 190. By means of laser scan and photoelectric method, the device reads the X-ray image data created in form of a latent image on the Plate exposed by an external X-ray generating device, and converts the read data into digital. The signal processing is made to the digital image data such as the digital filtering, the gain-offset correction and the shading collection. Then the REGIUS MODEL 190 is capable of transferring the image data to an externally connected device such as a host computer, an order input device, an image display device, a printer, an image data filing device, and other image reproduction devices.

For more information, please refer to the attachments.

9. Intended Use

The Direct Digitizer, REGIUS MODEL 190 is an X-ray image reader which uses a stimulable phosphor plate (Plate) as X-ray detector installed in a separate cassette. It reads the image recorded on the Plate and transfers the image data to an externally connected device such as a host computer, an order input device, an image display device, a printer, an image data filing device, and other image reproduction devices. It is designed intended to use in a clinic, a radiology department in a hospital and in other medical facilities.

10. Compliance standards

The Direct Digitizer, REGIUS MODEL 190 complies with the following standards:

Safety standard	: UL60601-1, IEC60601-1
Electromagnetic Compatibility	: FCC, IEC60601-1-2
Radiation safety	: 21 CFR 1040.10

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Konica Minolta Medical & Graphics, Inc.
% Mr. Shinichi Yamanaka
Cosmos Corporation-Progress Section
319 Akeno, Obata-cho
Watarai-gun, Mie-ken, 519-05
JAPAN

AUG 23 2013

Re: K042386
Trade/Device Name: Direct Digital REGIUS Model 190
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: November 24, 2004
Received: November 26, 2004

Dear Mr. Yamanaka:

This letter corrects our substantially equivalent letter of December 15, 2004.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known) :

Device Name : Direct Digitizer, REGIUS Model 190

Indications For Use:

The Direct Digitizer, REGIUS Model 190 is an X-ray image reader which uses a stimulable phosphor plate (Plate) as X-ray detector installed in a separate cassette. It reads the image recorded on the Plate and transfers the image data to an externally connected device such as a host computer, an order input device, an image display device, a printer, an image data filing device, and other image reproduction devices. It is designed and intended to be used by trained medical personnel in a clinic, a radiology department in a hospital and in other medical facilities. This device is not intended for use with digital mammography system.

Prescription Use ✓ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Seyman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K042386